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1501 K Street, NW
Washington, DC 20005

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,776,456

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,776,456, which claims the human biological product ZEVALIN® (CD20 Monoclonal antibody), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 227 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 227 days.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of April 21, 2003 (68 Fed. Reg. 19547), would be 900 days. Under 35 U.S.C. § 156(c):

Period of Extension	=	½ (Testing Phase) + Approval Phase
	=	½ (3363- 2039) + 476
	=	900 days (2.5 years)

Since the regulatory review period began December 7, 1992, before the patent issued (July 7, 1998), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From December 7, 1992, to and including, July 7, 1998, is 2039 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 900 days, would extend the patent from July 7, 2015 to December 23, 2017, which is beyond the 14-year limit (the approval date is February 19, 2002, thus the 14 year limit is February 19, 2016). The period of extension is thus limited to 227 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, July 7, 2015, to and including February 19, 2016, or 227 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 5,776,456

Granted:	July 7, 1998
Original Expiration Date[1]:	July 7, 2015
Applicant:	Darrel R. Anderson, et al.
Owner of Record:	IDEC Pharmaceuticals Corp.[2]
Title:	Therapeutic Application of Chimeric and Radiolabeled Antibodies to Human B Lymphocyte Restricted Differentiation Antigen for Treatment of B Cell Lymphoma
Product Trade Name:	ZEVALIN® (CD20 Monoclonal antibody)
Term Extended:	227 days
Expiration Date of Extension:	February 19, 2016

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

Attention: Beverly Friedman

RE: ZEVALIN® (CD20 Monoclonal antibody)
FDA Docket No.: 02E-0343

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[1]Subject to the provisions of 35 U.S.C. § 41(b).

[2]It is understood that IDEC Pharmaceuticals Corp. has changed its name to Biogen Idec Inc., however, the USPTO assignment database does not reflect this name change and, as such, if no change is made to the USPTO assignment database entry for U.S. Patent No. 5,776,456, the patent term extension will issue in the name of IDEC Pharmaceutical Corp.